Remarks

Claims 24-28 were pending in the subject application. By this Amendment, claims 12-30 have been canceled and new claims 31-42 have been added. The undersigned avers that no new matter is introduced by this amendment. Upon entry of this Amendment, claims 31-42 will be before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, the Office Action requests that the applicants provide the serial number and specific page numbers of any foreign application to which priority is claimed. However, pursuant to the Manual of Patent Examining Procedures (MPEP) §201.15, the applicants respectfully submit that there is no requirement that the applicants make such a showing absent a prior art rejection based on a reference with an effective date between the date of the particular foreign priority document and the effective U.S. filing date. No prior art rejection based on a reference with an intervening date has been set forth in the Office Action.

By this Amendment, the applicants have amended the claims portion of the specification to begin with the phrase "What is claimed is:". The Office Action indicates that the subject specification lacks an Abstract of the Disclosure and line numbering. Submitted herewith is a copy of the Preliminary Amendment filed June 15, 2001, which added an Abstract to the specification. Also submitted herewith is a copy of international application no. PCT/GB99/04377, from which the subject §371 application was filed in the U.S. Patent Office. The international application contains line numbers. The applicants respectfully request clarification regarding this objection.

Claims 24-28 are rejected under 35 U.S.C. § 112, first paragraph, as lacking sufficient written description. The applicants respectfully submit that the claimed invention is sufficiently described by the subject specification. However, by this Amendment, the applicants canceled claims 24-28, rendering this rejection moot.

New claims 31 and 37 recite that the homologue is obtainable from a Group B *Streptococcus* (GBS) and has at least 60% sequence similarity to SEQ ID NO:22. Support for new claims 31-42 can be found, for example, at page 3, lines 33-36, of the specification and in the claims as originally filed. Although the specific biological function of the recited peptide is not set forth, the specification clearly identifies a therapeutic function (see, for example, page 2, lines 6-10 and 34-37

of the specification). Moreover, the biological function of the peptide is irrelevant in the context of immunotherapy and does not provide any further information required to use the peptide to prevent or treat a bacterial infection. The subject invention is based upon the identification of the claimed peptide as an appropriate candidate for a vaccine composition, and this is set out clearly in the specification.

The applicants respectfully submit that homologues of GBS pho3-1 (SEQ ID NO:22) are described in the subject specification. As indicated in Example 11, at page 15 of the specification, homologues to the pho3-1 gene product have been identified from *Streptococcus pyogenes*, *Streptococcus pneumoniae*, and *Enterococcus faecalis*, for example. The applicants respectfully submit that one of ordinary skill in the art would appreciate that the applicants were in possession of the homologues recited in the currently pending claims. Methods for obtaining homologues and functional fragments of nucleotide sequences and amino acid sequences are well known in the art. For example, as indicated at page 4, lines 1-7 of the specification, homologues can be established by searching existing databases, such as the EMBL Nucleotide Sequence Database collaboration or GenBank of the National Center for Biotechnology Information (NCBI). With the benefit of the subject specification, fragments of the recited polynucleotide sequence and peptides encoded by such fragments can be obtained by one of ordinary skill in the art. The skilled artisan can determine suitable fragments that retain the immunogenic properties of the native molecule without resort to undue experimentation. Since prior to 1984, it has been well-known that *Bal*31 exonuclease can be conveniently used for time-controlled limited digestion of DNA. See for example, Maniatis, *et al.* (1982) *Molecular Cloning: A Laboratory Manual*, Cold Spring Harbor Laboratory, NY, pages 135-139. Given any known DNA sequence, the skilled artisan, by using *Bal*31 exonuclease, could easily have removed nucleotides from either or both ends of the DNA molecule to systematically, routinely, and certainly generate a wide spectrum of DNA fragments from all along the length of the molecule in one afternoon; and then introduce them into host cells. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 24-28 are rejected under 35 U.S.C. 112, first paragraph, as non-enabled by the subject specification. The applicants respectfully submit that the claimed subject matter is fully enabled by the subject specification. However, as indicated above, the applicants have cancelled claims 24-28,

rendering this rejection moot. New claims 31 and 37 recite that the homologue is obtainable from a Group B *Streptococcus* and has at least 60% sequence similarity to SEQ ID NO:22. Furthermore, submitted herewith for the Examiner's consideration is the Hughes *et al.* publication (*FEMS Microbiology Letters*, 2003, 222:263-271). The Hughes *et al.* publication is submitted herewith to verify the accuracy and sufficiency of what is taught in the specification as originally filed. As described at pages 267-268 and Figures 1 and 2 of the Hughes *et al.* publication, sera directed against the recited peptide (pho3-1) reacted against GBS. In the animal protection studies described at pages 268-269 and Figure 3 of the Hughes *et al.* publication, the results obtained using the pho3-1 peptide showed significant protection compared to the experimental control. Therefore, it is clear that the peptide recited in the claimed methods does in fact have the specified therapeutic utility, as taught by the subject specification. In view of the guidance provided in the subject specification, and the level of skill of those in the art, one of ordinary skill in the art could carry out the claimed methods without resort to undue experimentation. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

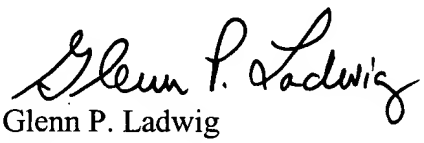
Claims 24-28 are rejected under 35 U.S.C. §112, second paragraph, as indefinite. The applicants respectfully submit that the claims are not indefinite. However, as indicated above, claims 24-28 have been cancelled, rendering this rejection moot. New claims 31-42 recite the polynucleotide of SEQ ID NO:22 or the amino acid sequence of SEQ ID NO:23, which is encoded by SEQ ID NO:22. Claims 31-36 are directed to a method for treatment of a condition associated with bacterial infection, and claims 37-42 are directed to a method for prevention of a condition associated with bacterial infection. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Petition and Fee for Extension of Time
Copy of Preliminary Amendment dated June 15, 2001
International application no. PCT/GB99/04377
Hughes *et al.* publication

Abstract of the Disclosure

According to the present invention, a series of genes are identified in Group B *Streptococcus*, the products of which may be associated with the outer surface of the organism. The genes, or functional fragments thereof, may be useful in the preparation of therapeutics, *e.g.* vaccines to immunize a patient against microbial infection.